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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,748	FRIEDE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-35,39-44 and 46-67* is/are pending in the application.

4a) Of the above claim(s) *64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35,39-44,46-63 and 65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In the prior action, claims 33-63 were under consideration to the extent that they read on the elected invention, and claims generic thereto. Claims 33-63 were rejected, and claim 64 was withdrawn as to non-elected inventions. In the Response, filed on August 16, 2004, the Applicant amended claims 33-35, 39-44, 46-56, and 58-61; cancelled claims 36-38, and 45; and added new claims 65-67.

2. Currently, claims 33-35, 39-44, and 46-67 are pending in the application. Claims 33-35, 39-44, 46-63, and 65-67 are under consideration, and claim 64 is withdrawn.

3. It is noted that the claims refer to "the European Union official criteria." Although this would normally be rejected as indefinite because the criteria are subject to change by the entity that established the criteria, no rejection is being made in the present case because the specification provides a clear definition of the criteria. See, Application page 4 (stating that "The European Union official criteria for an effective vaccine are set out in the table below," and providing a table illustrating the requirements of the criteria). In view of the fact that the specification defines the criteria both by name, and by specifying the requirements to be met, the claims meet the standard for definiteness with reference to the criteria language.

4. Because this action raises new grounds of rejection not necessitated by amendment, the action is being made Non-Final.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 33-44, 48, 50-63 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for because it was not clear from the application how the presently claimed influenza vaccines differ from the vaccines of the prior art. The Applicant argues that the claims are sufficiently clear in that they claim any split antigen influenza vaccine comprising a surfactant. The Applicant argues that the presence of the surfactant and the ability of the claimed vaccines to induce immune responses meeting the requirements of the European Union official criteria. The claims are therefore read as including any split antigen influenza vaccine comprising a surfactant as the application provides no additional structural limitations regarding the composition of the vaccines used in the claimed methods. The rejection is therefore withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 34 and 35 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment of the claims to clarify that the single dose must meet the European Union official criteria for only "one or more" of the included influenza strains.

7. **(Prior Rejection- Withdrawn)** Claims 38-42 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite as lacking sufficient antecedent basis for the phrase "wherein the formulation comprises..." In view of the cancellation of the phrase from the pending claims, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claim 39 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was unclear if the parenthetical statements were

intended as limitations to the claims. In view of the cancellation of the parenthetical limitations, the rejection is withdrawn.

9. **(Prior Rejection- Withdrawn)** Claim 43 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the phrase "such as" rendered the claim indefinite as it was unclear whether the limitations following the phrase are part of the claimed invention. In view of the amendment of the claim, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claims 44, 48, and 61 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of the use of the relative term "low" without providing a standard for ascertaining the requisite degree by which those in the art could determine what a low amount constituted. In view of the amendments to the claims, the rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claim 49 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for including broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation. In view of the amendment of the claims, the rejection is withdrawn.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. **(Prior Rejection- Maintained in part)** Claims 33-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods wherein two or more

administrations of the indicated antigen preparations or where a single administration of the preparations disclosed in examples 4 and 5 of the application are provided to a patient such that an immune response meeting the international regulatory requirements for influenza vaccines are met, does not reasonably provide enablement for methods where any single administration is made. The claims currently read on methods of administering a one-dose intranasal non-live influenza virus antigen preparation wherein the single dose meets at least one of the European Union Official criteria international regulatory requirements for influenza vaccines. The rejection is withdrawn to the extent that the claims are drawn to methods of administering dosages of at least 15 μg of HA, or to embodiments comprising at least 7.5 μg and either laureth-9 or MPL. However, the rejection is maintained to the extent that the claims read on the use of formulations comprising 7.5 μg in the absence of an immunostimulant or laureth-9, and to embodiments wherein the vaccine includes less than 7.5 μg of HA. Thus, the rejection is maintained against claims 33-35, 39-44, 46-63, and new claims 65-67.

The claims were rejected for two reasons. First that the application has not enabled the practice of the claimed methods to the extent that they read on embodiments wherein the vaccine comprises less than 30 μg of HA are provided or for embodiments where the vaccine does not include an immunostimulant. The examples in the application and the information in the Declaration of Dr. Van Hoeke have been considered. While these resources demonstrate that each of the vaccines tested by the application comprising 15 μg or more of HA, or comprising at least 7.5μg of HA in combination with an absorption enhancing surfactant or a surfactant and an immunostimulant, have achieved at least one of the European criteria, and that certain low dose intranasal vaccines have induced greater local immune responses than equivalent low dose

parenteral vaccines. However, these teachings neither establish that the low dose vaccines met even one of the European criteria, nor demonstrate that vaccines comprising less than 7.5 μg comprising any surfactant would achieve at least one of the European criteria.

With respect to the use of doses of 7.5 μg, the Applicant argues that the examples in the specification and the teachings in the declaration establish that at least one of the criteria was met with "even the lowest dose of haemagglutinin (7.5 μg per strain) without immunostimulant)." Response, pages 11. However, while this may be the case, it is noted that the example referred to, in each case of the use of 7.5 μg, the experimental data show the use of laurth-9, which is a surfactant known in the art for its ability to increase the ability of a protein to be absorbed by mucosa, and thereby increasing its ability to simulate an immune response. See e.g., Betbeder et al., U.S. 6,017,513, columns 9-10. Thus, it is not clear that dosages of as low as 7.5 μg would be able to induce such a response in the absence of any activity enhancing compound. While the claims are limited to embodiments comprising a non-ionic surfactant, the claims do not require that the surfactant has the ability to enhance the activity of the vaccine sufficient to meet the European criteria. Thus, while the submissions by the Applicant are persuasive to some extent, they are not sufficient to enable the full extent of the claims as they read on compositions comprising at least 7.5μg of HA in combination with any surfactant.

With respect to the use of any low dosage vaccine, it is noted that each of claims 44, 46, and 47 requires that the vaccine used in the claimed methods comprises "not more than" an indicated amount. Of particular note is claim 47, requiring that the composition administered comprise not more than about 7.5 μg of haemagglutinin. The Applicant has nowhere provided any evidence that any such low dose amount would be capable of achieving at least one of the

European criteria, with or without an immunostimulant or absorption enhancing surfactant. The data presented by the Applicant in Figures 2 and 4 demonstrate only that the responses to these intranasal low dose vaccines were equal to or greater than the equivalent low dose parenteral vaccine. The Applicant does not provide any indication that any of these vaccines met any of the European criteria. Nor does the Applicant provided any guidance as to what the lowest dosage of HA may be used, with or without additional ingredients, so that at least one of the criteria is met. In view of the scope of the claims, the lack of examples demonstrating that these low dose vaccines meet one or more of the criteria, or guidance as to what minimal HA dosages are required to meet at least one of the European criteria, and the teachings in the art indicating that low dose intranasal vaccine are not sufficient to provide a protective response, the Applicant has not provided sufficient information to enable those in the art to practice the claimed invention to the full extent covered by the claims.

14. **(Prior Rejection-Withdrawn)** Claims 33-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims currently read on a method of administering any split antigen influenza vaccine comprising a surfactant, and provide additional functional limitations on the operation of the method. For substantially the same reasons as indicated with respect to the indefinite rejection (paragraph 5) above, this rejection is withdrawn.

Claim Rejections - 35 USC § 102

15. **(Prior Rejection- Withdrawn)** Claims 33-38, 44-48, 50, 51, and 55-59 were rejected under 35 U.S.C. 102(b) as being anticipated by Oh et al., Vaccine 10(8): 506-11. The claims have been amended to require that the compositions comprise a surfactant. The Applicant traverses the rejection (inter alia) on the basis that the reference does not teach the inclusion of a surfactant in the administered vaccine. This argument is found persuasive. The rejection is therefore withdrawn.

16. **(Prior Rejection- Withdrawn)** Claims 33-38, 43-49, 51, and 55-58 were rejected under 35 U.S.C. 102(a) as being anticipated by the teachings of Glück et al., J Virol (supra). The claims have been described above. For the reasons above, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. **(Prior Rejection- Withdrawn)** Claims 38-40, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Oh or Glück as applied above, and further in view of Friede et al. (WO 99/52549- of record in the March 2002 IDS) These claims further limit the claimed methods to those wherein the one-dose anti-influenza preparations comprise the surfactant laureth 9, and/or the immunostimulant 3D-MPL. The Applicant argues that the Friede et al reference is not prior art against the present application in view of the priority claimed to the

earlier GB applications. This argument is found persuasive in view of the teachings GB 9922700.1. The rejection is therefore withdrawn.

19. **(Prior Rejection- Withdrawn)** Claims 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Oh or Glück in view of Friede as applied to claims 38-40, and 52-54 above, and further in view of either Baker et al. (U.S. 6,506,803) or Morein et al. (U.S. 5,679,354). The rejection is withdrawn for the reasons indicated with respect to the rejection over Oh or Glück in view of Friede above.

20. **(New Rejection- Necessitated by Amendment)** Claims 33-35, and 39-44, 46-52, 54-63, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oh and Glück as described previously, and further in view of the teachings of Betbeder et al. (U.S. 6,017,513) and Stern et al. (WO 97/33531). The teachings of Oh and Glück have been described in the prior action. While these references teach the intranasal administration of influenza vaccines, they do not teach the inclusion of surfactants in the vaccine formulations. However, each of Betbeder and Stern teach the addition of the indicated surfactants to vaccine compositions to increase the efficacy of the vaccines through improving the mucosal absorption of the antigens. Betbeder, columns 9-10; and Stern, pages 13-16. Because these references teach the use of one or more such absorption enhancers in protein vaccines, and because they specifically identify all of Triton X-100, Tween 80, laurth-9, and bile and cholic acids as examples of preferred enhancers, it would have been obvious to those in the art to use such surfactants in the vaccines of Oh and Glück. Additionally, the Betbeder reference also suggests the use of certain immunostimulants,

including MPL. It would therefore have been obvious to include such an immunostimulant in the intranasal vaccines.

It is noted that the references do not suggest that the claimed methods would be capable of achieving the desired protective results after a single administration. However, those in the art would have expected improved results from the use of the enhancers and immunostimulants described by the additional references. Thus, the references suggest the limitations of the claimed methods, which involve the administration of the described vaccines to a person to induce an immune response. The Applicant has discovered that a single administration of the vaccines is sufficient to induce an immune response that meets at least one of the European standards. It is not clear from the references if those in the art were aware of this characteristic of the suggested vaccines disclosed or suggested therein. However, because the references suggest the claimed methods, the Applicant's discovery of this additional benefit is not sufficient to demonstrate the non-obviousness of the claimed methods. See e.g., MPEP § 2145 II. This argument is therefore not found persuasive.

It s further noted that the Applicant continues to argue that the claims are drawn to "a method of successfully inducing a protective immune response ... against influenza infection by administering a single, intranasal dose of a vaccine containing these surfactants." Response, page 13. However, it is noted that the claims are nowhere limited to the administration of a single dosage of the "single dose" vaccine. Rather, the claims are drawn to a method "comprising" the administration of the vaccine formulation. While the Applicant has inserted the use of the descriptive term "single dose" and indicated that the intended response is achieved after a single administration, this does not exclude from the claimed methods embodiments wherein multiple

administrations of the vaccine are carried out. This is due to the use of the open transitional term "comprising" in the claim, and the lack of any other limitation in the claim excluding the later administration of additional doses. Thus, by arguing that the art does not teach the administration of a single dosage to achieve the desired results without excluding from the claims embodiments wherein multiple doses are administered, the Applicant is, as was pointed out above, essentially arguing the recognition of additional latent properties to the methods suggested by the prior art. The argument is therefore not found persuasive.

It is also noted that the Applicant alleges that the current claimed methods "achieve a significant level of immunity not seen with less than two doses of the Gluck vaccine." Page 13. In view of the combination of Glück with the teachings of Betbeder and Stern, this argument is not found persuasive. From the teachings of Stern and Betbeder regarding the additional use of absorption enhancing surfactants, those in the art would have expected improved results in the use of the vaccines. Additionally, the Glück reference based the "inadequacy" of their vaccine on the fact that the vaccine was less than that seen with the parenteral vaccine, and that two doses of the vaccine were better than one.

This is not adequate to distinguish from the Glück teachings for three reasons. First, as was noted above, the Glück reference nowhere makes any assertions, pro or con, with respect to the performance of the intranasal vaccine based on the European criteria. Thus, it is not clear that the vaccine of Glück was unable to achieve any of the European criteria. Rather, the best that can be said in that the authors felt that the intranasal vaccine was not as effective as the parenteral vaccine. Second, it is unclear how the teaching in Glück that two doses would be better than one teaches away from the claimed invention where the present claims do not exclude a second

administration, and where the Applicant provides no information as to whether the same would be true in the use of the vaccine formulations recited in the claims. Third, the data presented by the Applicant establishes that, in certain respects, the parenteral (intramuscular) administration of a vaccine equivalent to the formulations of the claimed methods still outperforms the claimed intranasal administrations. This can be seen from a comparison of the control (Group 5) in the clinical trail results on of the Van Hoecke Declaration with the results of the other Groups. Declaration, page 3, table of paragraph 7 (showing that the intramuscular administration achieved higher results in the measure of each of the conversion factor, seroconversion, and protection rate than any of the intranasal vaccines to which it was compared). For each of these reasons, it is not clear that the claimed methods have achieved results significantly greater than those that would have been expected based on the teachings of the cited prior art.

21. **(Prior Rejection-Restated as Necessitated by Amendment and Maintained)** Claims 50, and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Oh or Glück in view of Betbeder and Stern as applied above, and further in view of either of Baum et al. (U.S. 3,874,381) or Weinstein et al. (U.S. 5,437,267). These claims further describe the methods and kits described above, wherein the methods involves the administration of two subdoses of the vaccine, or the inclusion of an intranasal delivery device. The Applicant traversed the prior rejection on the grounds that "nothing in Baum or Weinstein suggests that the use of an intranasal device could achieve significant protection against influenza after only a single dose of vaccine." This argument is not found persuasive for the reasons indicated above. The rejection, as restated is therefore maintained.

22. **(New Rejection)** Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oh or Glück in view of Betbeder and Stern as applied above, and further in view of Hauser et al. (U.S. 5,776,468). This claim reads on the method of claim 33, wherein the vaccine further comprises the immunostimulant 3-0 deacylated monophosphoryl lipid A (3D-MPL). The teachings of Oh, Glück, Betbeder, and Stern have been described above. While the Stern reference suggests the use of MPL as an immunostimulant, the references do not teach or suggest the use of the immunostimulant 3D-MPL. Hauser does teach the use of this immunostimulant in vaccines, and suggests its use in anti-influenza vaccines. Columns 1, 4 (lines 14-25). Because this reference teaches the use of 3D-MPL as an adjuvant, and suggests its use in anti-influenza vaccines, and because Oh and Glück indicate that the vaccines therein would benefit from improved antigenicity, it would have been obvious to those in the art to reformulate the Oh and Glück compositions to include the immunostimulant disclosed by Hauser. Those in the art would have had a reasonable expectation of success in inducing an anti-influenza response through the combination of the intranasal administrations of Oh and Glück with the use of the immunostimulant disclosed in Hauser. The claim is therefore rendered obvious by the indicated references.

23. **(New Rejection- Necessitated by Amendment)** Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oh or Glück in view of Betbeder and Stern as applied above, and further in view of either of Modi et al., (U.S. 5,653,987) or Illum (U.S. 5,690,954). This claim further limits the methods of claim 33, wherein the vaccine composition comprises a

bile or cholic acid or derivative thereof, and in particular, wherein the cholic acid is sodium deoxycholate. As indicated above, each of Betbeder and Stern indicates that, among the absorption enhancers that may be used to improve the uptake of vaccines into the mucosa are bile and cholic acids. However, neither of these references, nor Oh or Glück, specifically teach or suggest the use of sodium deoxycholate.

The use of sodium deoxycholate as an absorption enhancer would have been obvious when the above references are further considered in view of either Modi or Illum Each of these references provides additional teachings regarding the use of absorption enhancers in pharmaceutical compositions. Additionally, each also identifies sodium deoxycholate as an effective enhancer. Modi, abstract; and Illum, column 2, lines 53-67. In view of these teachings, and the suggestions in Betbeder and Stern that bile and cholic acids may be used as absorption enhancers in vaccines, it would have been obvious to those in the art to include this composition in the intranasal vaccines of Oh or Glück in order to achieve improved antigen results using the intranasal vaccines.

24. **(Prior Rejection- Withdrawn)** Claims 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Barrett et al. (WO 00/47222) in view of either Baum or Weinstein as applied against claims 50, and 61-63 above. For the purposes of this rejection, reference will be made to U.S. Patent 6,635,246, which is a U.S. Patent in English filed from the international application published in German as WO 00/47222. The Applicant traversed the rejection on the Basis that Barrett is not prior art against the claims in view of the claim to

priority to the earlier UK applications. The argument is persuasive. The rejection is therefore withdrawn.

25. **(Prior Rejection- Withdrawn)** Claims 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Chatfield (WO 97/16208) in view of Barrett, Baum, Weinstein as applied against claims 61-63 above. Claim 59 teaches that the kit described above includes a non-live influenza antigen preparation that does not include an added immunostimulant. The rejection is withdrawn for the reasons indicated with respect to the rejection over Barrett, Baum, and Weinstein above.

Conclusion

26. No claims are allowed.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 11/15/04